K051380

AUG 3 0 2005

stryker Howmedica OSTEONICS

325 Corporate Drive
Mahwah, NJ USA 07430

510(k) Summary of Safety and Effectiveness for the Triathlon® Total Knee System

Proprietary Name:	Triathlon™ Total Knee System
Common Name:	Total Knee Joint Replacement Prosthesis
Classification Name and Reference	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis. 21 CFR §888.3565
Regulatory Class:	Class II
Device Product Code:	87 MBH - prosthesis, knee, patello/femorotibial, semi-constrained, uncemented, porous, coated, polymer/metal/polymer,
For Information contact:	Tiffani Rogers Regulatory Affairs Specialist Stryker Orthopaedics 325 Corporate Drive Mahwah, New Jersey 07432 Phone: (201) 831-5412 Fax: (201) 831-6038 E-Mail: Tiffani.Rogers@stryker.com
Date Summary Prepared:	August 11, 2005

Device Description

The Triathlon® Total Knee System will be available with femoral and tibial components in a cementless design with and without Stryker Howmedica Osteonics' Peri-apatite (PA) coating. The Triathlon® fixed bearing cementless baseplate and femoral components are compatible with the current Triathlon® tibial inserts and patellas. The Triathlon® components proposed in this submission are manufactured from cast cobalt chrome and have a cobalt chrome porous coating, available with and without a PA coating. The Triathlon® tibial component is fixed bearing and will be provided in sizes 1 through 8.

The femoral components will be offered in both cruciate retaining (CR) and posterior stabilizing (PS) versions, also in sizes 1 through 8.

Intended Use:

The Triathlon® Total Knee System is intended for use in primary and revision total knee arthroplasty to alleviate pain and restore function. The Triathlon® Total Knee System is intended for cementless use only.

Indications

- Painful, disabling joint disease of the knee resulting from: noninflammatory degenerative joint disease (including osteoarthritis, traumatic arthritis or avascular necrosis) or rheumatoid arthritis.
- Post-traumatic loss of knee joint configuration and function.
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability.
- Revision of previous unsuccessful knee replacement or other procedure.
- Fracture of the distal femur and/or proximal tibia that cannot be stabilized by standard fracture management techniques.

Additional Indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

Substantial Equivalence:

The determination of the substantial equivalence of the Triathlon® Total Knee System is based on its similarities in intended use, design and sterilization to Howmedica Osteonics' Triathlon® PS Total Knee System (K042993, cleared January 12, 2005), Triathlon® CR Total Knee System (K040267, cleared May 05, 2004), Duracon® Total Knee System (K032163, cleared September 12, 2003 and K032418 cleared, September 11, 2003). Predicate device information is located in **Appendix D**.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2005

Ms. Tiffani Rogers
Regulatory Affairs Specialist
Howmedica Osteonics Corp.
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K051380
Trade/Device Name: Triathlon® Total Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: MBH
Dated: August 11, 2005
Received: August 13, 2005

Dear Ms. Rogers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K051380

Device Name: Triathlon® Total Knee System

Indications

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Additional Indications for Posterior Stabilized Components:

- Ligamentous instability requiring implant bearing surface geometries with increased constraint.
- Absent or non-functioning posterior cruciate ligament.

The Triathlon® Total Knee System beaded and beaded with Peri-apatite components are intended for uncemented use only.

Prescription Use X OR Over-the-Counter Use

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051380